REMARKS

Claims

Claims 1, 5-6, 10-11, 29-31, 38-41, and 44 remain in the application with claims 1 and 44 being independent. Claims 1, 6, 10-11, and 40 have been amended. Claims 2-4, 7-9, 12-28, 32-37, and 42-43 have been canceled. Claim 44 has been added. Reconsideration of the pending claims is respectfully requested.

Claim Rejections - 35 U.S.C. §103(a)

Claims 1, 2, 4-6, 8-12, and 28-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wellisz et al. (U.S. Pat. No. 6,511,482) in view of Hair (U.S. Pat. No. 6,197,037). Claims 10 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wellisz et al. in view of Hair and in further view of Pohndorf et al. (U.S. Pat. No. 5,904,683). Claims 1, 2, 4, 8-9, 12, 28, 32-37, and 42-43 have been canceled. Thus, the rejection as to these claims is now moot. Applicant respectfully traverses the rejection to claim 1.

Claim 1, as amended, recites a self-retaining implant 10 for attaching a bone cover or a bone fragment to a skull. The implant comprises a support element 12 having an upper side 18 and a lower side 20. An extension 14 extends substantially at a right angle from the lower side 20 of the support element 12 to an end remote from the support element 12 and substantially straight between the support element 12 and the end. At least one spike 16 extends substantially parallel to the support element 12 such that the spike 16 can be driven laterally into the bone cover or bone fragment **prior to positioning the bone cover or bone fragment adjacent to the skull**. The support element 12 further comprises two support arms 22, 24 extending in opposite directions from the extension with the first 22 of the two support arms defining a screw hole 26 therein for receiving a fastener to secure the first support arm 22 to the skull **after the spike 16 has been driven laterally into the bone cover or bone fragment and after positioning the bone cover or bone fragment adjacent to the skull**. The second 24 of the two support arms cooperates with the bone cover or bone fragment

when driving the spike 16 into the bone cover or bone fragment.

Wellisz et al. discloses an implant 120 for attaching a bone flap to a skull. The implant 120 of Wellisz et al. comprises a support element 121 having two support arms, an extension 223 extending in a curved fashion downwardly from a lower side of the support element 121 to a remote end, and a barb 223a extending at an acute angle from the remote end of the extension. Multiple implants 120 are used to attach the bone flap to the skull. In this process, each of the implants 120 of Wellisz et al. are first attached to the bone flap by way of a screw with the barbs 223a protruding outwardly from the bone flap. Then, with the implants 120 secured to the bone flap, the bone flap is positioned in the skull and the barbs engage the skull in a "snap-fit" manner to hold the bone cover or bone fragment in position. Wellisz et al. does not disclose driving a spike into the bone flap **prior to positioning the bone flap adjacent to the skull**, nor does Wellisz et al. disclose securing the first support arm to the skull **after the spike has been driven laterally into the bone flap and after positioning the bone flap adjacent to the skull**, as now required by claim 1. The barbs 223a of Wellisz et al. grip the skull, not the bone flap, through surface contact when positioning the bone flap adjacent to the skull (see FIG. 11). In other words, Wellisz et al. does not teach first driving the barbs laterally into the bone flap, then positioning the bone flap adjacent to the skull, and then securing the first support arm by way of a fastener. In fact, the barbs 223a are not configured to engage the bone flap in any fashion. To do so would ruin their intended "snap-fit" engagement with the skull.

Furthermore, to serve their intended function, the barbs 223a of Wellisz et al. cannot extend substantially parallel to the support element 121, as required by claim 1. If they did, they would not provide the gripping force required for the "snap-fit" engagement between the bone cover or bone fragment and the skull. The Examiner states that it would have been obvious to form the barbs at an angle of 90 degrees from the extension, e.g., substantially parallel to the support element 121, since "it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." (page 3 of office action). However, Applicant respectfully submits, for the reasons presented above, that forming the barbs 223a at an angle of 90

degrees from the extension 223 would defeat the "snap-fit" engagement of the barbs 223a in Wellisz et al. With the barbs 223a at an angle of 90 degrees to the extension 223, when the bone flap is positioned in the skull, the barbs 223a would scrape against the edges of the skull, as opposed to smoothly gliding into position, as provided by their disclosed angular orientation.

The Examiner notes that Wellisz et al. does not disclose the extension 223 extending substantially straight between the support element 121 and the remote end, as also required by claim 1. As a result, the Examiner has applied to the teachings of Hair to reject claim 1.

Hair discloses a fastener for joining a bone flap to a skull. The fastener includes a support element having two support arms for fitting over an upper bone layer of the bone flap and the skull, an extension extending straight from the support element to a remote end, and a second support element at the remote end having two support arms for fitting below a bottom bone layer of the bone flap and the skull. The Examiner has applied the teachings of the straight extension in Hair to Wellisz et al. to arrive at claim 1. Like Wellisz et al., however, Hair also fails to disclose driving a spike into the bone flap **prior to positioning the bone flap adjacent to the skull** or securing the first support arm to the skull **after the spike has been driven laterally into the bone flap and after positioning the bone flap adjacent to the skull**, as now required by claim 1. Thus, even if these references could be properly combined, they do not teach or suggest all of the limitations required by claim 1, as currently amended.

Finally, even if all of the limitations required by claim 1 were found in Wellisz et al. and Hair, when combined, there is no teaching, suggestion, or motivation for these references to be properly combined to establish a prima facie case of obviousness. In the "BACKGROUND OF THE INVENTION", Wellisz et al. stresses the disadvantages of implants that protrude below the bottom bone layer of the skull or bone flap to compress the underlying brain tissue. In other words, one of the important features of their implant is that it does not protrude below the bottom bone layer and come into contact with the brain tissue. Hair, on the other hand, specifically shows the second support element 60 extending below the bottom bone layer (see, e.g., FIG. 3) for positioning between the bottom bone layer and

the brain tissue. Hence, these references teach away from one another and lack any motivation, teaching, or suggestions to be combined.

In summary, neither Wellisz et al., nor Hair, disclose driving a spike into a bone cover or bone fragment **prior to positioning the bone cover or bone fragment adjacent to a skull** or securing a first support arm to the skull **after the spike has been driven laterally into the bone cover or bone fragment and after positioning the bone cover or bone fragment adjacent to the skull**, as now required by claim 1. Furthermore, there is no teaching, suggestion, or motivation in these references to combine the references as suggested by the Examiner. In fact, these references teach away from one another. Wellisz et al. teaches an implant that must not contact the brain tissue, and Hair teaches an implant that is disposed adjacent the brain tissue. For these reasons, Applicant respectfully submits that independent claim 1 is in condition for allowance.

Applicant respectfully submits that dependent claims 5-6, 10-11, 29-31, and 38-41 are also placed in condition for allowance based on their own merits, and their dependency to allowable claim 1.

Applicant respectfully submits that new independent claim 44 is also placed in condition for allowance. This is a new method claim that recites all of the structure required by claim 1 and the steps employed to attach the implant and secure the bone cover or bone fragment to the skull.

Applicant believes the application is now in condition for allowance, which allowance is respectfully solicited. Applicant believes that no additional fees are required, however, the Commissioner is authorized to charge our Deposit Account No. 08-2789 for any additional fees or credit the account for any overpayment.

Respectfully submitted,

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